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IN THE
Supreme Court of the United States

SERGEANTS BENEVOLENT ASSOCIATION HEALTH AND WELFARE FUND, ON BEHALF OF THEMSELVES AND OTHERS SIMILARLY SITUATED, ET AL.,
Petitioners,

v.

ELI LILLY AND COMPANY,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

In marketing its prescription drug Zyprexa, respondent made fraudulent claims about the drug's safety and effectiveness and promoted the drug for uses for which it had not been approved by the Food and Drug Administration. Respondent pleaded guilty to criminal misbranding charges and paid hundreds of millions of dollars to the federal government to reimburse losses suffered by government health-care programs. Petitioners in this case are pension funds, labor unions, and insurance companies that paid for Zyprexa prescriptions on behalf of their insureds or members. Petitioners brought this action under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1964(c), to recover their losses resulting from respondent's fraud.

The questions presented are:

1. Whether the court of appeals erred in relying on the causation analysis in the Chief Justice's partial opinion for the Court in *Hemi Group, LLC v. City of New York*, 130 S. Ct. 983 (2010), to hold — contrary to this Court's unanimous decision in *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008) — that petitioners could not establish the causation element of their RICO claim because the presence of prescribing physicians in the chain of causation constituted an intervening factor breaking the link between respondent's fraudulent marketing and petitioners' foreseeable injuries.

2. Whether, alternatively, this petition should be held for *Erica P. John Fund, Inc. v. Halliburton Co.*, No. 09-1403 (U.S. granted Jan. 7, 2011), and disposed of in light of the Court's decision in that case, because the court below — like the Fifth Circuit in *Halliburton* — based its denial of class certification on the conclusion that petitioners could not establish the causation element of their claim on the merits.

PARTIES TO THE PROCEEDINGS

Sergeants Benevolent Association Health and Welfare Fund, on behalf of themselves and others similarly situated; UFCW Local 1776 and Participating Employers Health and Welfare Fund; Eric Tayag and Mid-West National Life Insurance Company of Tennessee, on behalf of themselves and others similarly situated; and Local 28 Sheet Metal Workers, on behalf of themselves and others similarly situated, were the plaintiffs and the appellees below.

Eli Lilly and Company was the defendant and the appellee below.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6 of the Rules of this Court, Mid-West National Life Insurance Company of Tennessee states the following:

Mid-West National Life Insurance Company of Tennessee ("Mid-West") is a wholly owned subsidiary of HealthMarkets, LLC, which is a wholly owned subsidiary of HealthMarkets, Inc. Mid-West is licensed to sell health and life insurance policies in Puerto Rico, the District of Columbia, and all States except Maine, New Hampshire, New York, and Vermont. HealthMarkets, Inc. is owned by a group of private equity investors.

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Sergeants Benevolent Association Health and Welfare Fund, UFCW Local 1776 and Participating Employers Health and Welfare Fund, Mid-West National Life Insurance Company of Tennessee, and Local 28 Sheet Metal Workers, on behalf of themselves and others similarly situated, respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

INTRODUCTION

This case concerns the ability of private health-benefit providers — also referred to as "third-party payors" or "TPPs" — to bring claims for fraud in the marketing of prescription drugs. Third-party payors — pension funds, labor unions, and insurance companies, such as petitioners — paid for respondent's drug Zyprexa on behalf of their insureds or members. In marketing Zyprexa, respondent made misleading claims about the drug's safety and effectiveness and aggressively marketed the drug for uses for which it had not been approved by the Food and Drug Administration ("FDA"). In 2009, respondent pleaded guilty to federal criminal charges relating to its promotion of Zyprexa for unapproved uses. As part of a global resolution of government suits, it agreed to pay $1.415 billion in fines, penalties, and compensation, including hundreds of millions of dollars to reimburse federal government health-insurance providers for losses they suffered in paying for Zyprexa prescriptions on behalf of government employees.

Petitioners brought this suit under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1964(c), to recover their losses resulting from respondent's fraud. The Second Circuit below held that private third-party payors cannot seek

relief on a class-wide basis because the "independent actions" of the physicians who prescribed Zyprexa constitute an intervening factor that precludes petitioners from establishing the causation element of their RICO claim. Under the court of appeals' standard, petitioners would have to show that "*they* relied" directly on respondent's misrepresentations. App.[1] 24a. The court below rested on that same line of reasoning in holding that the district court should have granted summary judgment to respondent on petitioners' claim to recover overcharges for Zyprexa prescriptions. The decision below thus turned on a structural feature of the health-care system — namely, that third-party payors pay for drugs, but do not choose them, whereas physicians choose drugs, but do not pay for them.

This Court's review is warranted. The court of appeals' holding conflicts with *Bridge v. Phoenix Bond & Indemnity Co.*, 553 U.S. 639 (2008). In *Bridge*, this Court held that a RICO plaintiff need not prove its own reliance, either as an element of its claim or as a means of demonstrating causation. It also held that a plaintiff's claim is sufficiently direct to permit recovery, despite the presence of other factors in the causal chain, so long as the plaintiff's injury was "a *foreseeable* and natural consequence of" the defendant's misconduct. *Id.* at 658 (emphasis added). Here, petitioners paid for Zyprexa prescriptions and thus were the foreseeable — indeed, the primary — party that suffered direct economic harm as a consequence of respondent's overcharges and off-label promotion.

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[1] "App." refers to the separately bound appendix to this petition; "C.A. App." refers to the appendix filed in the Second Circuit.

In reaching a result contrary to *Bridge*, the court of appeals relied on *Hemi Group, LLC v. City of New York*, 130 S. Ct. 983 (2010). The Chief Justice's partial opinion for the Court in that case rejected "foreseeability" as a standard for proximate causation under RICO, without addressing *Bridge*. *Id.* at 991. But Justice Ginsburg, who provided the necessary fifth vote supporting the Court's judgment in that case, declined to "subscrib[e] to the broader range of the Court's proximate cause analysis," including the discussion of foreseeability. *Id.* at 995 (Ginsburg, J., concurring in part and concurring in the judgment). The court below failed even to acknowledge that limitation on *Hemi*'s holding. In reading *Hemi* to require a result that conflicts with *Bridge*, the Second Circuit not only erred but also laid bare the uncertainty generated by the fractured decision in *Hemi*. Unless resolved by this Court, that uncertainty will only spawn further confusion and disuniformity in the lower federal courts regarding the standard for causation in a RICO action.

In addition, the decision below raises a recurring issue of substantial importance to the health-care system. Private third-party payors such as petitioners spend more than half a trillion dollars per year to pay for prescription drugs and other treatments on behalf of their beneficiaries. But the Second Circuit's approach severely limits the ability of third-party payors to pursue federal remedies for health-care fraud resulting in unnecessary and overpriced prescriptions.

That draconian result stands in stark contrast to the outcome for governmental third-party payors. Respondent has agreed to pay hundreds of millions of dollars to reimburse federal government health

programs such as Medicaid for losses resulting from respondent's off-label promotion of Zyprexa. As a policy matter, functionally denying relief to private payors for proven fraud while permitting governmental payors to recover substantial compensation is entirely unjustified. Moreover, courts in other circuits have upheld recoveries for third-party payors harmed by pharmaceutical companies' fraud. The decision below thus raises the prospect of a third-party payor's claim succeeding or failing depending on the forum in which it is brought.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-30a) is reported at 620 F.3d 121. The memorandum and order of the district court denying motions for summary judgment (App. 382a-397a) is reported at 493 F. Supp. 2d 571; the memorandum and order of the district court granting in part and denying in part a motion for class certification (App. 31a-381a) is reported at 253 F.R.D. 69.

JURISDICTION

The court of appeals entered its judgment on September 10, 2010. A petition for rehearing was denied on November 12, 2010. App. 398a. On February 1, 2011, Justice Ginsburg extended the time within which to file a petition for a writ of certiorari to and including March 25, 2011. App. 402a. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant provision of RICO, 18 U.S.C. § 1964, is reproduced at App. 400a-401a.

STATEMENT

Petitioners purchased large quantities of respondent's prescription drug Zyprexa on behalf of their insureds and members. They brought this action for damages under RICO, alleging that respondent had made misrepresentations regarding Zyprexa's safety and efficacy and had illegally promoted Zyprexa for uses not approved by the FDA. In separate orders, the district court denied respondent's motion for summary judgment and certified a class of third-party payors seeking to recover overpayments for Zyprexa resulting from respondent's alleged fraud. The court of appeals reversed the district court's class-certification order and vacated its summary judgment order.[2]

A. Respondent's Fraudulent Marketing Of Zyprexa

1. As the court of appeals observed, the "market for prescription drugs" is "significantly different" from markets "for typical consumer goods" because "direct exchanges between consumers and producers are rare." App. 7a. "An individual patient does not choose what drug to take; she is prescribed a drug by her physician." *Id.*; *see* App. 200a. Prescription drugs are typically paid for not by the patients who take them or the physicians who prescribe them, but by third-party payors such as petitioners. *See* App. 36a.

Although third-party payors cover "most spending for drugs," they "usually exert only indirect control over therapeutic choice." App. 212a. A third-party

[2] Given the procedural posture, the Court views the facts in the light most favorable to petitioners. *See Brosseau v. Haugen*, 543 U.S. 194, 195 n.2 (2004) (per curiam).

payor typically pays for a prescribed medication only if the drug is authorized under its formulary, a list of medications approved for payment. *See* App. 8a. That formulary is usually managed by a pharmacy benefit manager (or "PBM"), which has a committee made up of physicians and clinical pharmacists that approves particular drugs for inclusion in the formulary. *Id.* Pharmacy benefit managers maintain their formularies "based upon publicly available clinical information, which is in large part produced and disseminated by the drug manufacturers themselves." *Id.* Although a third-party payor has the ability to make changes in its formulary, "in practice TPPs rarely modify the recommendations of their PBMs." *Id.*; *see* App. 204a.

When it comes to antipsychotics such as Zyprexa, third-party payors have even less discretion in determining what prescriptions they will cover. As the court of appeals acknowledged, "[p]atients respond to antipsychotic drugs in an individualized manner, and patients with the same disease may respond to the same medication in very different ways." App. 9a. Consequently, third-party payors — and the pharmacy benefit managers that manage the formularies of drugs approved for reimbursement by those payors — "are reluctant to exclude antipsychotic drugs from their formularies, or to place financial conditions on their use." *Id.*; *see* App. 200a-202a, 205a-209a.

2. This case involves olanzapine, a so-called "second generation" antipsychotic prescription drug that respondent markets under the brand name Zyprexa. In 1996, the FDA first approved Zyprexa for treatment of schizophrenia, and it approved the drug for long-term treatment of schizophrenia in 2000. *See* App. 94a. In 2000 and 2004, the FDA approved

Zyprexa for short-term and long-term (respectively) treatment of bipolar disorder. *See* App. 94a-95a.

Before the 1990s, so-called "first generation" antipsychotics were the standard drug therapy for schizophrenia. *See* App. 92a. The efficacy of first-generation antipsychotics is limited, and they have a number of significant adverse side effects, including movement disorders such as Tardive Dyskinesia. *See id.* Consequently, researchers sought to develop new medicines that would be safer and more effective. *See* App. 93a. Those efforts led to the introduction of second-generation antipsychotics, such as clozapine (approved by the FDA in 1989) and risperidone (approved in 1993). *See* App. 93a-94a. All antipsychotics, both first generation and second generation, function primarily by targeting dopamine receptors in the brain. *See* App. 92a; C.A. App. A857.

Although intended to be an improvement over existing therapies, Zyprexa is in fact no more efficacious or safe than comparable antipsychotics. With respect to efficacy, the studies on which respondent relied in obtaining the FDA's initial approval of Zyprexa were, in the words of one FDA official, "insufficient to permit [respondent] to make claims asserting the product's superiority" over the first-generation antipsychotic haloperidol. App. 130a (internal quotation marks omitted). In fact, respondent's studies did not even attempt to show that Zyprexa worked better than other antipsychotics. *See* App. 128a-130a; *see also* App. 3a, 250a, 255a-256a. Instead, those studies showed only that Zyprexa was superior to a placebo in the management of symptoms of psychotic disorders in patients with schizophrenia. *See* App. 128a-129a. Subsequent research confirmed that Zyprexa was only about as effective as other

second-generation antipsychotics. *See* App. 114a, 169a-170a, 184a-185a, 220a.

With respect to side effects, Zyprexa — like other antipsychotics — carries significant risks of movement disorders. *See* App. 169a-170a, 185a. And Zyprexa is associated with serious weight gain, diabetes, and related disease states; indeed, the incidence of those metabolic side effects is higher with Zyprexa than with other antipsychotics. *See* App. 166a, 170a-173a, 179a, 185a, 277a; *see also* App. 4a-5a. Zyprexa also presents serious risks of death in the elderly. *See* App. 180a-182a.

Those side effects were known to respondent during the relevant time period. For example, respondent's own studies conducted before the FDA approved Zyprexa revealed the association with weight gain. *See* App. 127a-128a, 254a-255a. One such study showed that patients who began taking Zyprexa gained, on average, one and a half pounds per week. *See* App. 128a.[3]

Despite those facts about Zyprexa's safety and efficacy, respondent marketed Zyprexa as more effective, and safer, than other comparable antipsychotic drugs. For example, on October 1, 1996, the day

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[3] Respondent successfully resisted the FDA's pre-approval recommendation to list weight gain in the "precautions" section of the label for Zyprexa. Weight gain was instead relegated to the "adverse reactions" section, which lists nearly every side effect that occurs in clinical trials. *See* App. 131a-133a; *see* 21 C.F.R. § 201.57(f)-(g) (1996). Listing weight gain only as an adverse reaction "de-emphasized Zyprexa's demonstrated association with this side effect." App. 132a. By October 2007, weight gain and hyperglycemia (increased blood sugar levels) would be elevated to the "warnings" section of the label. *See* 21 C.F.R. § 201.57(c)(6) (2006) (warnings section contains "clinically significant adverse reactions").

after the FDA initially approved Zyprexa, respondent held a teleconference during which one of its officials implied that Zyprexa "was superior in efficacy [to] and lack[ed] [the] side effects [of] other antipsychotics." App. 133a. The FDA issued a warning letter shortly thereafter, in which it informed respondent that certain comments at the teleconference were "'false and misleading.'" *Id.* (quoting letter from FDA official to respondent). The FDA found respondent's promotional campaign for Zyprexa to be "'lacking in appropriate balance, thereby creating a misleading message about Zyprexa.'" App. 134a (quoting FDA letter). The agency particularly objected to "'implications of superiority over other antipsychotic products that are unsubstantiated'" and to the presentation of Zyprexa as "'superior, highly effective, [and] virtually free of side effects.'" App. 135a (quoting FDA letter); *see* App. 3a-4a.

Undeterred, respondent continued its misleading marketing campaign. Respondent engaged in a coordinated effort to "systematically maximize[] Zyprexa sales by influencing the sources of information that doctors are trained to trust." App. 267a-268a. It sponsored medical research, journal articles, and continuing medical education courses, all in an effort to influence prescribing physicians. *See* App. 226a-229a, 267a-268a; C.A. App. A1748-A1754; *see also* App. 104a-115a. Respondent also withheld information from, and provided misleading information to, the FDA regarding Zyprexa's side effects. *See* App. 139a-147a, 157a-159a, 190a-195a.

Respondent employed a sales force of more than 2,000 representatives and instructed them to communicate specific messages about Zyprexa to physicians. *See* C.A. App. A1782-A1787. Those messages

included telling physicians that the risks of weight gain were the same for all second-generation antipsychotics (which is not true). *See id.* An analysis of the sales representatives' call notes reflects the remarkable consistency of those misleading messages. *See id.* at A1789-A1817. Respondent's "expensive promotional efforts were driven by a sense of urgency: with its patent for former bestseller Prozac running out, Zyprexa's success was crucial to [respondent's] future." App. 102a.

3. Respondent relied on its misrepresentations regarding Zyprexa's safety and efficacy to set and maintain a "premium price" for the drug. An internal memorandum outlined respondent's pricing practices:

> A premium price requires justification, and pharmacoeconomics is the cornerstone. The availability and persuasiveness of health economics data will enable Zyprexa to command a premium price in all customer segments. Without these data, we risk therapeutic substitution among the atypical [i.e., second-generation] antipsychotics and will not achieve our strategic intent.

C.A. App. A1910-A1911. As respondent's expert explained: "When a product delivers better outcomes, it deserves to be priced at a premium relative to competitors. Should the outcomes not differ from competitive products, a parity price is in order." App. 286a; *see* App. 9a ("One doctor who discussed the launch price with [respondent] before Zyprexa was put on the market recalled a . . . senior employee [of respondent] explaining the higher price as 'premium drug, premium price,' meaning that Zyprexa's high price was justified by its assertedly superior

performance as compared to other antipsychotic drugs then on the market."); C.A. App. A1634.

Thus, as the district court found, the record in this case contains evidence that, "but for [respondent's] misconduct, the launch price of Zyprexa would have been set at markedly lower levels than its major competitors." App. 304a. Instead, however, Zyprexa's initial prescription price was $77 more than the cost of other second-generation antipsychotics. *See* App. 9a. The initial launch price is critical because "[t]he initial price set by a pharmaceutical company is 'sticky'" and often "does not respond to [decreases in] market demand." App. 6a; *see* App. 98a-99a. As respondent continued to tout Zyprexa's supposed superiority and suitability for off-label uses, it increased the drug's price at a greater rate than manufacturers of other second-generation antipsychotics, so that by 2003 Zyprexa was selling for $292 per prescription, $113 more than the prices of Zyprexa's three main competitor drugs. *See* App. 9a-10a.

4. Respondent also promoted Zyprexa for uses that had not been approved by the FDA. Federal law prohibits pharmaceutical manufacturers from marketing a drug for such "off-label" uses. *See* 21 U.S.C. §§ 331(a), (d), 355. Respondent's marketing nevertheless urged physicians to prescribe Zyprexa for off-label uses — for example, to treat symptoms of depression, anxiety, irritability, or agitation; as a "mood stabilizer" for certain types of patients, including adult women; and to treat dementia in the elderly. *See* App. 10a-12a, 148a-153a. Respondent specifically targeted primary-care physicians, who generally do not treat patients with schizophrenia or bipolar disorder (the only two conditions that the FDA had approved Zyprexa to treat). *Id.* "Rather than adver-

tising its use for specific disorders, [respondent] marketed Zyprexa for symptoms commonly encountered by [primary-care physicians], encouraging doctors to treat patients without making a diagnosis at all." App. 150a. Consequently, "[b]y 2002, almost two-thirds of Zyprexa prescriptions for bipolar disorder were for off-label uses." App. 12a; *see also* App. 154a ("[Respondent's] marketing efforts succeeded in greatly increasing the number of off-label sales of the drug; without off-label marketing, Zyprexa — originally approved for the treatment of conditions affecting less than one percent of the population — could not have become the seventh best-selling drug in the world.").

After the truth about Zyprexa's safety and suitability for off-label uses began to emerge, the number of prescriptions written for Zyprexa decreased markedly. In September 2003, the FDA required respondent and other manufacturers of second-generation antipsychotics to add a warning concerning hyperglycemia and diabetes to their labels. *See* App. 5a. In May 2005, the FDA required those manufacturers to add a "black box warning" — which is used for risks that may lead to serious injury or death, *see* 21 C.F.R. § 201.57(e) (2005) (now codified at § 201.80(e)) — concerning the increased risk of death in elderly patients taking second-generation antipsychotics for dementia. *See* App. 5a. Following those labeling changes, prescriptions of Zyprexa plummeted, decreasing by approximately 50 percent from 2003 to 2008. *See* App. 165a-166a.

B. The District Court's Summary Judgment And Class-Certification Orders

In 2005, petitioners sued respondent, asserting claims under RICO and state law and seeking to

recover their losses resulting from respondent's deceptive and illegal marketing practices. *See* App. 51a-63a. Petitioners presented evidence and expert testimony supporting two primary damages theories: (i) petitioners paid higher prices for Zyprexa prescriptions than they would have paid absent the fraud (the "overpricing" theory), and (ii) petitioners paid for prescriptions of Zyprexa that would not have been written without the fraud (the "quantity" theory). *See* App. 391a.

In June 2007, the district court denied respondent's motion for summary judgment. *See* App. 382a-397a. Relevant here, the court determined that genuine issues of material fact existed regarding the causation element of petitioners' RICO claim. *See* App. 388a-392a. It explained that "[t]he alleged injury is direct: [petitioners] overpaid from their own funds for Zyprexa because of [respondent's] fraud." App. 389a. The court thus held that petitioners could seek as damages "the difference between the price they paid for Zyprexa and the price they would have paid for Zyprexa but for [respondent's] alleged fraud." App. 392a. In that order, the district court did not address petitioners' quantity theory of damages.

In September 2008, the district court granted in part petitioners' motion for class certification. *See* App. 31a-381a. The record before the district court was massive, comprising 1,151 exhibits, 317 depositions, 82 expert reports, and the live testimony of eight expert witnesses. In an opinion spanning 150 pages in the Federal Rules Decisions, the district court certified a class of non-governmental entities that, "pursuant to a contract, policy or plan," paid or reimbursed "all or part of the cost of Zyprexa prescribed, provided, or administered to natural persons

covered by such contract, policy or plan" from June 2001 to June 2005. App. 356a. The district court limited its certification order to petitioners' RICO claim seeking to recover overcharges. *See* App. 32a-33a. It denied petitioners' motion to the extent it sought certification on the quantity theory or on state-law claims. *See* App. 33a-34a, 356a-357a. It also declined to certify a class of individual patients (who paid for Zyprexa through co-payments). *See* App. 357a.

The district court rejected respondent's argument that causation cannot be shown through common proof: "Proof in the instant case is not generalized. [Petitioners] were directly injured by [respondent] when each was overcharged a fixed computable amount for each prescription." App. 320a; *see also* App. 335a ("Overpayments will be computed for all purchases, whether on- or off-label."). Relying on *Bridge*, the court also explained that it did not matter whether petitioners themselves relied directly on misrepresentations by respondent, because "[t]here is ample evidence that fraud was directed through mailings and otherwise at doctors who relied, causing damages in overpayments by [petitioners]." App. 316a; *see also* App. 308a-309a ("[In *Bridge*,] [t]he Court held that the person who suffered the loss need not be the one to whom the fraudulent words were directed. The instant case is a perfect example of that proposition. The fraud was directed to prescribing doctors. The overpayments were made by [petitioners].") (citations omitted).[4]

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[4] The district court certified its summary judgment order for interlocutory appeal under 28 U.S.C. § 1292(b). *See* App. 349a-352a.

C. The Second Circuit's Decision

The court of appeals granted respondent leave to appeal both the order granting class certification and the order denying summary judgment. *See* App. 16a-17a; *see also* Fed. R. Civ. P. 23(f); 28 U.S.C. § 1292(b). It reversed the class-certification order, vacated the summary judgment order, and remanded for further proceedings.

Relying heavily on *Hemi*, which was decided after oral argument in the court below, the Second Circuit held that the existence of prescribing physicians in the causal chain prevented petitioners from establishing the causation element of their RICO claim. That fundamental conclusion underpinned each of the court's holdings. With respect to class certification on the overpricing theory, the court of appeals reasoned that prescribing physicians' reliance on respondent's "misrepresentations as to the efficacy and side effects" of Zyprexa could not have been "a but-for cause of the price that [petitioners] ultimately paid for each prescription," because "prescribing doctors do not generally consider the price of a medication when deciding what to prescribe for an individual patient." App. 23a. The court also stated that, as it understood the record, proximate causation could not be shown because, "[c]rucially," petitioners "do not allege that *they* relied on [respondent's] misrepresentations — the misrepresentations at issue were 'directed through mailings and otherwise at doctors.'" App. 24a (quoting App. 316a). Regarding petitioners' quantity theory of damages, the court of appeals similarly opined that class certification would be unwarranted because the chain of causation was "interrupted" by "the independent actions of prescribing physicians." App. 26a.

The Second Circuit then turned to the district court's order denying summary judgment. The court summarily concluded, on the basis of its earlier analysis, that, to the extent petitioners sought to recover for overcharges, their RICO claim was too indirect to satisfy the requirement of proximate causation. *See* App. 29a ("[a]fter *Hemi Group*, it is clear that plaintiffs' overpricing theory is too attenuated"). The Second Circuit recognized, however, that the district court had not addressed the quantity theory of damages in its summary judgment order. The court of appeals "decline[d] to consider whether summary judgment with respect to [that] theory is appropriate in the first instance" and accordingly remanded that issue for further proceedings. *Id.*

REASONS FOR GRANTING THE PETITION

I. THE COURT OF APPEALS' JUDGMENT CONFLICTS WITH THIS COURT'S DECISION IN *BRIDGE* ON A RECURRING ISSUE OF SUBSTANTIAL IMPORTANCE TO THE NATION'S HEALTH-CARE SYSTEM

The court of appeals' decision in this case exposes the uncertainty created by this Court's decisions in *Bridge* and *Hemi*. The Second Circuit's determination that petitioners cannot prove causation without establishing their own reliance on respondent's misrepresentations conflicts with *Bridge*, in which this Court rejected such a reliance requirement and concluded that RICO's proximate-cause element is satisfied where the plaintiff's injury was a foreseeable result of the defendant's misconduct. In relying on *Hemi* to support a result that is irreconcilable with *Bridge*, the decision below exacerbated the uncertainty and confusion sown by the fractured decision in *Hemi*. Further, the effect of the court of appeals'

holding is to restrict severely, if not eliminate entirely, federal remedies for private third-party payors that are defrauded by pharmaceutical companies. Unlike the Second Circuit, courts in other circuits have upheld recoveries for third-party payors in similar circumstances. Thus, following the decision below, the ability of third-party payors to recover for health-care fraud may depend on the circuit in which the action is brought.

A. The Second Circuit's Causation Analysis Conflicts With *Bridge*

The court of appeals' decision conflicts with this Court's decision in *Bridge*.

1. *Bridge* involved a county's procedures for auctioning tax liens and implicates the same type of alleged intervening factors the Second Circuit found dispositive here. The auctions in *Bridge* were so competitive that multiple prospective buyers routinely bid the lowest possible price, forcing the county to allocate the liens on a rotational basis. To ensure that each bidder got its fair share of the liens, the county prohibited bidders from using agents to submit multiple bids for the same lien (the so-called "Single, Simultaneous Bidder Rule"). A dispute arose between two regular participants in the auctions, one of which accused the other of violating the Single, Simultaneous Bidder Rule by arranging for related firms to submit additional bids. The defendant argued that the plaintiff's RICO claim failed because "the alleged misrepresentations — [the defendant's] attestations of compliance with the Single, Simultaneous Bidder Rule — were made to the county, not [the plaintiff]." 553 U.S. at 648. Consequently, the plaintiff "could not have," and

indeed did "not even allege that" it had, "relied on [the defendant's] false attestations." *Id.*

The unanimous Court in *Bridge* rejected the contention that a civil RICO plaintiff alleging fraud "must show that [it] relied on [the defendant's] fraudulent misrepresentations." *Id.* It explained that the defendant's proposed reliance requirement "c[a]me out of nowhere" and had no support in the text of the relevant statutory provisions. *Id.*; *see id.* at 648-49. The Court concluded that "a person can be injured 'by reason of' a pattern of mail fraud even if he has not relied on any misrepresentations." *Id.* at 649.

The *Bridge* Court also rejected the notion that a showing of reliance is "necessary to ensure that there is a sufficiently direct relationship between the defendant's wrongful conduct and the plaintiff's injury to satisfy . . . proximate-cause principles." *Id.* at 657-58. It explained that the plaintiff's "alleged injury — the loss of valuable liens — is the direct result of [the defendant's] fraud" because it was "a foreseeable and natural consequence of [the defendant's] scheme to obtain more liens for [itself] that other bidders would obtain fewer liens." *Id.* at 658.

2. Each of the Second Circuit's rulings turned on its view that the existence of prescribing physicians broke the causal chain connecting respondent's fraud and petitioners' losses. *See* App. 22a-28a. But, under *Bridge*, petitioners' injuries are "the direct result of [respondent's] fraud" because they were "a foreseeable and natural consequence of" respondent's scheme to charge inflated prices for, and to promote off-label prescriptions of, Zyprexa. 553 U.S. at 658; *see also Brown v. Cassens Transp. Co.*, 546 F.3d 347, 357 (6th Cir. 2008) (post-*Bridge* decision holding that

proximate causation is shown under RICO where "the defendants' fraudulent acts were a substantial and foreseeable cause of the injuries alleged by the plaintiffs") (internal quotation marks omitted), *cert. denied*, 130 S. Ct. 795 (2009). The Second Circuit failed even to acknowledge that governing standard.

Petitioners' injuries — overpayments for Zyprexa and payments for excess off-label Zyprexa prescriptions — plainly were "foreseeable and natural consequence[s] of" respondent's fraudulent scheme to overcharge for Zyprexa and to promote Zyprexa illegally for off-label uses. Indeed, the chain of causation here is clear and direct: respondent set and maintained inflated prices for Zyprexa based on its misleading claims about Zyprexa's safety and effectiveness, and it promoted Zyprexa for off-label uses; physicians, induced by respondent's claims, prescribed Zyprexa to their patients; and third-party payors, such as petitioners, paid for those Zyprexa prescriptions. Petitioners thus are the direct victims of respondent's fraudulent scheme. As in *Bridge*, the presence of an additional actor in the causal chain — here, prescribing physicians; there, the county — does not defeat causation or enable the defendant to avoid responsibility for the foreseeable consequences of its fraud. *See Staub v. Proctor Hosp.*, 131 S. Ct. 1186, 1192 (2011) ("A cause can be thought 'superseding' only if it is a cause of independent origin that was not foreseeable.") (internal quotation marks omitted); *see also Sosa v. Alvarez-Machain*, 542 U.S. 692, 704 (2004) ("[A] given proximate cause need not be, and frequently is not, the exclusive proximate cause of harm.").

Further, under *Bridge*, it does not matter whether petitioners themselves relied on respondent's fraudu-

lent statements: "a plaintiff asserting a RICO claim predicated on mail fraud need not show, either as an element of its claim or as a prerequisite to establishing proximate causation, that it relied on the defendant's alleged misrepresentations." 553 U.S. at 661. Therefore, the court of appeals' assertion that it is "[c]rucial[]" that (in the court's view) petitioners did "not allege that *they* relied on [respondent's] misrepresentations" (App. 24a) cannot be squared with *Bridge*.[5]

The remaining reasons invoked by the Second Circuit do not eliminate the conflict between the decision below and *Bridge*. First, the court thought that reliance by petitioners is required because only third-

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[5] The plaintiffs' claims in *Holmes v. Securities Investor Protection Corp.*, 503 U.S. 258 (1992), and *Anza v. Ideal Steel Supply Corp.*, 547 U.S. 451 (2006), suffered from defects not present here. In *Holmes*, the injuries in question were "purely contingent on the harm suffered by" a third party. 503 U.S. at 271. Petitioners' injuries are not derivative of harm to any other party; rather, petitioners themselves paid for the overpriced and illegal prescriptions. In *Anza*, the cause of the plaintiff's "asserted harms" was "a set of actions . . . entirely distinct from the alleged RICO violation." 547 U.S. at 458. In contrast, petitioners' losses — i.e., overpayments for prescriptions and payments for prescriptions that would not have been written — were caused by the same actions that constitute the alleged RICO violation — i.e., respondent's fraudulent and illegal marketing of Zyprexa. Moreover, none of the reasons that supported the decisions in *Holmes* and *Anza* supports the Second Circuit's decision here. There is no "independent[] factor[]" — such as the broker-dealers' "poor business practices" in *Holmes* — that accounts for the losses of which petitioners complain. *Holmes*, 503 U.S. at 269, 273; *see Anza*, 547 U.S. at 458-59. Nor is there a risk of multiple recoveries, as there was in *Holmes*, because only petitioners made the payments in question. Finally, here, there is no more directly injured party — like the broker-dealers (*Holmes*) or the State of New York (*Anza*) — that is better situated to vindicate the law.

party payors "were in a position to negotiate the price paid for Zyprexa." App. 24a. That notion disregards the fact — which the court elsewhere acknowledged, *see* App. 9a — that, given the nature of antipsychotic drugs, third-party payors were not in a position to refuse to pay for Zyprexa, making negotiations over price pointless. In any event, the record shows that petitioners, no less than prescribing physicians, were misled by respondent's claims. *See* App. 319a ("[T]he evidence supports a finding of an overcharge based on the fraud on doctors, third-party payors, and others.").

Second, the Second Circuit's belief that "but for" causation is lacking here because doctors do not consider price, *see* App. 23a, is a *non sequitur*. Physicians relied on respondent's claims about safety, efficacy, and suitability for off-label uses in prescribing Zyprexa. Those factors enabled respondent to set and maintain a "premium price" for the drug. *See supra* pp. 10-11. Whether physicians also considered Zyprexa's price in prescribing the drug is beside the point.

Third, the court of appeals' speculation (App. 26a-28a) that other "variables" could have affected the number of excess prescriptions for which a given third-party payor paid ignores the well-settled rule that, where (as here) the fact of harm can be shown, issues relating to the calculation of damages neither preclude class certification[6] nor justify summary judgment for the defendant.[7] Notably, the court did

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[6] *See, e.g.*, 7AA Charles A. Wright et al., *Federal Practice and Procedure* § 1778, at 122-25 (3d ed. 2005); *Carnegie v. Household Int'l, Inc.*, 376 F.3d 656, 661 (7th Cir. 2004) (Posner, J.).

[7] *See, e.g.*, *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264-66 (1946); *Restatement (Second) of Torts* § 912 cmt. a (1979).

not suggest that there might be third-party payors that paid for *no* excess prescriptions. Similarly, respondent need not be "the *only* source of information" (App. 27a) for prescribing doctors, because the court below did not suggest (nor could it have) that the vast numbers of excess prescriptions would still have been written even without respondent's off-label marketing or that the off-label marketing was not a substantial factor in those excess prescriptions. *See Staub*, 131 S. Ct. at 1192 ("[I]t is common for injuries to have multiple proximate causes.").

Accordingly, had the court below applied *Bridge*'s foreseeability standard, it would have affirmed the district court's judgment certifying the class and rejecting respondent's summary judgment motion.

B. The Second Circuit's Reliance On *Hemi* Increases Confusion Regarding The Governing Causation Standard Under RICO

1. Instead of following *Bridge*, the Second Circuit relied heavily on this Court's recent decision in *Hemi*. Decided just two Terms after *Bridge*, *Hemi* produced a fractured Court. The Chief Justice delivered the opinion of the Court "in part," 130 S. Ct. at 986, which only three Justices joined without reservation. Justice Ginsburg concurred in part and concurred in the judgment. *See id.* at 994. Justice Breyer dissented, joined by Justices Stevens and Kennedy. *See id.* at 995. And Justice Sotomayor took no part in the consideration or decision of the case. *See id.* at 994.

In *Hemi*, the City of New York sued the Hemi Group, an online retailer of cigarettes, alleging that Hemi had violated the federal Jenkins Act by failing to report to the State of New York information on its online sales of cigarettes to New York residents. The

City alleged that, had Hemi reported that information to the State, the State would have provided it to the City, enabling the City to collect from Hemi's customers local taxes on cigarettes. (No law required Hemi to charge, collect, or remit tax on its cigarette sales in New York, and Hemi's customers rarely paid the tax voluntarily.) The City asserted that Hemi's Jenkins Act violations ultimately resulted in less tax revenue for the City.

The Chief Justice's partial opinion for the Court concluded that the City's claimed injury was too remote to satisfy the requirement of proximate causation under RICO because "the conduct directly causing the harm" — "the customers' failure to pay their taxes" — "was distinct from the conduct giving rise to the fraud" — "Hemi's failure to file Jenkins Act reports." *Id.* at 990. Further, the Chief Justice noted that the Court's prior decisions had "highlighted as relevant to the RICO 'direct relationship' requirement . . . whether better situated plaintiffs would have an incentive to sue," and he pointed out that, there, "[t]he State certainly is better situated than the City to seek recovery from Hemi." *Id.*

The Chief Justice's opinion also posited that "RICO's proximate cause requirement" should not "turn on foreseeability," asserting that such an approach was unsupported by the Court's prior decisions. *Id.* at 991. That aspect of his opinion, however, did not mention the unanimous decision in *Bridge*, which had held that Phoenix Bond's injury was "the direct result of [Bridge's] fraud" because it was "a foreseeable and natural consequence of [Bridge's] scheme." 553 U.S. at 658.

Concurring in part and in the judgment, Justice Ginsburg declined to "subscrib[e] to the broader

range of the Court's proximate cause analysis." *Hemi*, 130 S. Ct. at 995. In her view, because the fraud the City alleged was "based on violations of . . . the Jenkins Act, . . . the nature and consequences of the fraud are [properly] determined solely by the scope of that Act." *Id.* at 994 (internal quotation marks omitted; alterations in original). Justice Ginsburg thus rejected "reading RICO to allow the City to end-run its lack of authority to collect tobacco taxes from Hemi Group or to reshape the quite limited remedies Congress has provided for violations of the Jenkins Act." *Id.* at 995 (internal quotation marks omitted). Justice Ginsburg joined the Court's opinion only "to the extent it is consistent with [that] view" and otherwise "concur[red] in the Court's judgment." *Id.* Because Justice Ginsburg "concurred in the judgment[] on the narrowest ground[]," her "position" is best viewed as the "holding of the Court" in *Hemi*. *Marks v. United States*, 430 U.S. 188, 193 (1977) (internal quotations marks omitted).

In his dissenting opinion, Justice Breyer concluded that Hemi's fraudulent failure to report tax information to the State proximately caused the City's lost tax revenue because that loss was a "foreseeable" consequence of Hemi's misconduct. 130 S. Ct. at 996-97 (Breyer, J., dissenting). He explained that, in *Bridge*, the Court "held," in permitting the plaintiff's claim in that case to proceed, "that the harm was 'a foreseeable and natural consequence of [the defendants'] scheme.'" *Id.* at 1000 (quoting *Bridge*, 553 U.S. at 658) (brackets added by Justice Breyer).

2. Relying on *Hemi*, the court of appeals here opined that the presence of physicians and others in the causal chain precluded a showing of causation. *See* App. 23a-24a. But the Second Circuit failed even

to acknowledge that the "broader range" of the causation analysis in the Chief Justice's opinion in *Hemi* was not joined by a majority of the Court. *Hemi*, 130 S. Ct. at 995 (Ginsburg, J., concurring in part and concurring in the judgment); *see supra* pp. 23-24. The Chief Justice's opinion thus could not have overruled *Bridge*'s holding that the requirement of proximate cause is met when, as here, the plaintiff's injury is "a foreseeable and natural consequence of" the defendant's misconduct. *Bridge*, 553 U.S. at 658. In reading *Hemi* to support a conclusion that cannot be squared with *Bridge*, the Second Circuit's decision creates great confusion regarding the governing standard for causation in a civil RICO action.

As the Second Circuit's decision illustrates, the inconsistency in the analyses in *Bridge* and the Chief Justice's partial opinion for the Court in *Hemi* is real. In *Bridge*, the unanimous Court reasoned that the plaintiff's alleged injury was "the direct result of [the defendant's] fraud" because "[i]t was a *foreseeable* and natural consequence of" the defendant's scheme. 553 U.S. at 658 (emphasis added). In *Hemi*, however, the Chief Justice's opinion rejected the notion that "RICO's proximate cause requirement [should] turn on foreseeability," without even mentioning *Bridge*. 130 S. Ct. at 991. Justice Ginsburg's opinion did not mention foreseeability at all, instead grounding the result in a rationale specific to the Jenkins Act. And Justice Breyer's dissent advocated a foreseeability standard, citing *Bridge*. The confusion created by the conflict in those opinions necessarily cannot be resolved without this Court's intervention. Left unresolved, that disagreement among the Justices will continue to produce divergent results and uncertainty in the lower federal courts.

C. The Court Of Appeals' Decision Drastically Limits The Ability Of Private Payors To Recover For Health-Care Fraud

Modern health care is increasingly mediated through private health-benefit providers that do not make, but must pay for, health-care decisions. In 2008 alone, personal health-care expenditures in the United States totaled nearly $2 trillion, and private health insurance paid more than 35 percent of those expenditures (or more than $690 billion).[8] Yet the Second Circuit's decision denies those private health-insurance providers a federal remedy for health-care fraud that results in inflated prices for treatment. Under the court of appeals' approach, the existence of prescribing physicians in the chain of causation renders a third-party payor's overpricing claim too remote as a matter of law. But the separation between prescribing decisions (which are made by doctors) and responsibility for payment (which resides in many cases with third-party payors such as petitioners) is a structural feature of our Nation's health-care system. Thus, the deficiency that the court below found in petitioners' claim will be present in every case in which a third-party payor seeks to recover for fraudulent marketing of a prescription medication.

This case is an excellent example of the irrationality of precluding non-governmental third-party payors from seeking relief for losses caused by fraudulent and illegal marketing. In January 2009, the Department of Justice announced that respondent had agreed to pay $1.415 billion to settle criminal charges

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[8] *See* U.S. Dep't of Health & Human Servs., *Health, United States, 2010*, at 7, 32, 75, 371 (Feb. 2011), *available at* http://www.cdc.gov/nchs/data/hus/hus10.pdf#highlights.

and civil actions arising from its promotion of Zyprexa for off-label uses.[9] Respondent pleaded guilty to the criminal charge of misbranding and agreed to pay a criminal fine of $515 million — the largest ever paid by an individual corporation. *See* DOJ Press Release at 1, 2. Respondent also agreed to pay more than $430 million to settle civil suits in which the federal government alleged that respondent had defrauded governmental third-party payors such as Medicaid and the Federal Employee Health Benefits Program. *Id.* Those suits were brought under the False Claims Act, which creates a fraud-based cause of action in favor of the government. *Id.* Thus, on the same facts regarding respondent's off-label marketing of Zyprexa, governmental third-party payors have recovered hundreds of millions of dollars in payments for prescriptions, whereas private third-party payors such as petitioners may recover nothing.[10]

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[9] *See* U.S. Dep't of Justice, Press Release, *Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-Label Promotion of Zyprexa* (Jan. 15, 2009) ("DOJ Press Release"), *available at* http://www.justice.gov/opa/pr/2009/January/09-civ-038.html.

[10] To be sure, having concluded that class certification on petitioners' quantity theory of damages for off-label promotion would be inappropriate, the court of appeals "decline[d] to consider whether summary judgment with respect to [that] theory is appropriate in the first instance." App. 29a. Even so, eliminating the ability of third-party payors to litigate as a class renders actions against pharmaceutical manufacturers infeasible. *See* App. 329a ("Denial of certification would constitute a death knell for third-party payor claims.").

D. Other Courts Of Appeals Have Upheld Recoveries By Third-Party Payors In Similar Circumstances

Third-party payors have sought damages for overcharges for prescription medications in numerous cases, and multiple courts of appeals and other federal courts have upheld recoveries in such cases.

1. *Seventh Circuit.* In *In re Synthroid Marketing Litigation*, a pharmaceutical company falsely represented that no comparable drug was bioequivalent to its drug Synthroid, thereby deterring physicians from prescribing cheaper substitutes. A class of third-party payors sued the pharmaceutical company, asserting claims under civil RICO (among other laws). The district court granted class certification. *See* 188 F.R.D. 287 (N.D. Ill. 1999). In so doing, it rejected the drug maker's argument that class certification was inappropriate because "causation depends upon individualized inquiries into decisions of consumers, physicians and pharmacists to purchase, prescribe and dispense Synthroid," pointing out that "[i]ndividual reliance . . . is not an element of . . . a RICO claim predicated on acts of mail or wire fraud." *Id.* at 292 (internal quotation marks omitted). The parties subsequently agreed to a settlement in which the drug maker would pay $46 million to the third-party payors, and the Seventh Circuit affirmed the district court's judgment approving that settlement, over various objections. *See In re Synthroid Mktg. Litig.*, 264 F.3d 712 (7th Cir. 2001).

Third Circuit. In *In re Warfarin Sodium Antitrust Litigation*, 391 F.3d 516 (3d Cir. 2004), third-party payors alleged that a drug manufacturer (DuPont) had disseminated false and misleading information about the safety of a lower-priced generic competitor

of one of its prescription drugs (Coumadin). The third-party payors brought claims under federal antitrust laws, as well as state antifraud statutes.[11] And they sought damages on behalf of a class of "all similarly situated U.S. TPPs who paid for the fulfillment of Coumadin prescriptions for their members or their insureds at supracompetitive prices." *Id.* at 524. The parties settled the case, with DuPont agreeing to pay $45 million to resolve the claims of TPPs and consumers.

On appeal of the district court's approval of the settlement, the Third Circuit rejected objectors' arguments that certification of a class of purchasers of Coumadin was inappropriate because common questions did not predominate, explaining that "the causal linkage between DuPont's conduct and the injury suffered by the class members" was a question "common to the entire class." *Id.* at 528; *see id.* at 529 ("DuPont's alleged deceptive conduct arose from a broad-based, national campaign conducted by and directed from corporate headquarters, and individual reliance on the misrepresentations was irrelevant to liability."). In addition, objectors specifically challenged "the inclusion of TPPs in the certified class."

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[11] RICO's requirement of proximate causation is based on a similar requirement applicable in antitrust suits. *See Holmes*, 503 U.S. at 266-68 (relying on *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519 (1983), an antitrust case). It is therefore to be expected that pharmaceutical manufacturers will contend that the Second Circuit's causation analysis in this case applies equally to antitrust claims by third-party payors against drug companies. Regardless, third-party payors often do not purchase drugs directly from manufacturers and are consequently precluded from seeking damages under federal antitrust laws. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977).

Id. at 531. The Third Circuit rejected those challenges as well, noting that "TPPs, like individual consumers, suffered direct economic harm when, as a result of DuPont's alleged misrepresentations, they paid supracompetitive prices for Coumadin." *Id.*[12]

2. Under the decision below, those cases presumably would have come out differently: the existence of prescribing physicians in the causal chain would have led the courts to reject the third-party payors' claims for failure to establish causation. The decision below thus creates great uncertainty over the ability of third-party payors to recover for losses resulting from fraudulent marketing of prescription drugs. And, as the cases cited above illustrate, disputes between pharmaceutical manufacturers and third-party payors arise with frequency.[13]

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[12] Multiple additional federal decisions have certified classes of third-party payors in actions alleging overcharges for prescription drugs. *See, e.g., In re Lupron Mktg. & Sales Practices Litig.*, 228 F.R.D. 75, 78 (D. Mass. 2005) (certifying class and approving settlement); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 332 (E.D. Mich. 2001) (certifying class); *In re Cardizem CD Antitrust Litig.*, 218 F.R.D. 508, 517, 530 (E.D. Mich. 2003) (certifying class and approving settlement), *aff'd in part and appeal dismissed in part on other grounds*, 391 F.3d 812 (6th Cir. 2004); *In re Lorazepam & Clorazepate Antitrust Litig.*, 205 F.R.D. 369, 402 (D.D.C. 2002) (certifying class and approving settlement); *see also* App. 337a-349a.

[13] A recent Eleventh Circuit decision involving facts materially indistinguishable from those here has deepened the confusion in the lower courts on the ability of third-party payors to recover for health-care fraud. The court held that third-party payors failed to plead an actionable injury resulting from the defendant drug company's fraudulent marketing because their complaint did not negate the inference that they set and collected premiums to compensate for the risk of having to pay for fraudulent prescriptions. *See Ironworkers Local Union 68 v. AstraZeneca*

Civil actions brought by third-party payors provide a reasonable remedial response to instances, such as this one, of proven abuse by drug manufacturers. Without this Court's intervention, the decision below will stand as a precedent for denying private third-party payors an effective federal remedy for health-care fraud.[14] The ability of non-governmental third-party payors to recover for health-care fraud is an important and recurring issue that warrants this Court's immediate consideration.

II. ALTERNATIVELY, THIS PETITION SHOULD BE HELD PENDING RESOLUTION OF *ERICA P. JOHN FUND, INC. v. HALLIBURTON CO.* BECAUSE IT IMPLICATES THE SAME ISSUE OF WHETHER CAUSATION CAN BE CONSIDERED AT THE CLASS-CERTIFICATION STAGE

This Court recently granted review in *Erica P. John Fund, Inc. v. Halliburton Co.*, No. 09-1403 (U.S. granted Jan. 7, 2011), to decide whether a plaintiff can be required to prove causation to establish its entitlement to class certification. This case implicates that issue because the court below similarly relied on a causation analysis in reversing the district court's order granting class certification. In the

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Pharms., LP, No. 08-16851, 2011 WL 833222, at *3, *7-*9 (11th Cir. Mar. 11, 2011) (to be reported at — F.3d —). Judge Martin concurred in the result only; he would have followed the reasoning of the decision below. *See id.* at *10 (Martin, J., concurring in the result).

[14] This case has already been the subject of commentary in scholarly and trade publications. *See* Shawn S. Ledingham, Jr., Note, *Aggregating Reliance and Overcharges: Removing Hurdles to Class Certification for Victims of Mass Fraud*, 85 N.Y.U. L. Rev. 289 (2010); Linda S. Mullenix, *A Recent Blow for Third-Party-Payor Plaintiffs*, Nat'l L.J., Oct. 18, 2010, at 32.

event the Court does not grant this petition to decide the first question presented, then the petition should be held and disposed of in light of *Halliburton*.

The issue presented in *Halliburton* involves whether a court can consider the merits of the causation element of a plaintiff's claim at the class-certification stage, where causation does not relate to any of the prerequisites for class certification under Rule 23. Unlike in civil RICO actions, a securities-fraud plaintiff must prove reliance. *See Basic Inc. v. Levinson*, 485 U.S. 224, 243 (1988). This Court has held that, in a securities-fraud action involving a publicly traded security, investors' reliance on public misrepresentations can be presumed. *See id.* at 247. Investors often rely on that presumption in obtaining class certification because, when it applies, the *Basic* presumption eliminates the need to demonstrate that each investor's reliance can be shown through common proof.

In *Halliburton*, the Fifth Circuit held that, before a plaintiff can rely on the *Basic* presumption to obtain class certification, the plaintiff must "establish loss causation" — that is, "that the complained-of misrepresentation or omission materially affected the market price of the security." *Archdiocese of Milwaukee Supporting Fund, Inc. v. Halliburton Co.*, 597 F.3d 330, 335 (5th Cir. 2010) (internal quotation marks omitted), *cert. granted sub nom. Erica P. John Fund, Inc. v. Halliburton Co.*, 131 S. Ct. 856 (2011). The Fifth Circuit did not ground that requirement in Rule 23. The investor in *Halliburton* successfully sought this Court's review, arguing that the Fifth Circuit's rule "unnecessarily" requires a decision on "the merits of the underlying claim" at the class-certification stage. Pet. for Cert. at 2, *Halliburton*,

supra (U.S. filed May 13, 2010) (No. 09-1403), 2010 WL 2007735; *see also Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177 (1974) ("We find nothing in either the language or history of Rule 23 that gives a court any authority to conduct a preliminary inquiry into the merits of a suit in order to determine whether it may be maintained as a class action."); Fed. R. Civ. P. 23 advisory committee's note (2003 Amendments) ("an evaluation of the probable outcome on the merits is not properly part of the certification decision").

This case implicates the issue presented in *Halliburton*. Here, too, the court of appeals based its determination that class certification was inappropriate on the ground that petitioners had not established the causation element of their claim on the merits. Although the court below made references to an inability to show causation through "generalized proof," App. 22a, the opinion as a whole leaves no doubt that the class-certification decision was premised on a merits conclusion — namely, the belief that the presence of prescribing physicians in the causal chain precluded petitioners from establishing the causation element of their claim on the merits. *See* App. 22a-28a; *supra* pp. 15-16. The court of appeals' primary authority for that conclusion, *Hemi*, did not involve class certification. And the brevity of the court of appeals' discussion in reversing the denial of summary judgment on the overpricing theory, *see* App. 28a-29a, confirms that the court's class-certification analysis turned on the merits of the causation issue, not on any supposed inability to demonstrate causation through common proof. Further, that *Halliburton* involves a claim for securities fraud is of no moment, because loss causation in a securities-fraud action is closely analogous to

the RICO causation issues involved here. *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346 (2005).

Accordingly, if the Court concludes in *Halliburton* that causation cannot be considered independent of the requirements of Rule 23 in determining the propriety of granting class certification, then this petition should be granted, the judgment below should be vacated, and the case remanded for reconsideration in light of *Halliburton*. *See Lawrence v. Chater*, 516 U.S. 163, 167 (1996) (per curiam) (recognizing that a decision to grant, vacate, and remand may be warranted when an intervening decision of this Court "reveal[s] a reasonable probability that the decision below rests upon a premise that the lower court would reject if given the opportunity for further consideration"); *id.* at 180-81 (Scalia, J., dissenting) (describing with approval this Court's "regular[]" practice of "hold[ing] cases" and then granting, vacating, and remanding them when an intervening decision of this Court "cast[s] doubt on" the decision below).

CONCLUSION

The petition for a writ of certiorari should be granted. Alternatively, the petition should be held pending resolution of *Erica P. John Fund, Inc. v. Halliburton Co.*, No. 09-1403, and then disposed of as appropriate in light of the Court's decision in that case.

Respectfully submitted,

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